DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 2, 2015

Dexin Medical Imaging Technology Co., Ltd.
% Mr. Leon Lu
Director of Quality and Regulatory Affairs
MEDevice Services, LLC
3500 South Dupont Highway
DOVER DE 19901

Re: K143586
Trade/Device Name: FACT Medical Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 18, 2015
Received: August 4, 2015

Dear Mr. Lu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143586

Device Name

FACT Medical Imaging System

Indications for Use *(Describe)*

The FACT Medical Imaging System is a medical software application that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. The FACT Medical Imaging System is not meant for primary image interpretation in mammography.
In addition, the FACT Medical Imaging System has the following indications:

(1) Pulmonary Review and Analysis Application
Pulmonary Review and Analysis application is an option that is intended for supporting physicians in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from pulmonary CT images. Three-Dimensional segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, and reporting tools are combined with a dedicated workflow.
The automated image registration facilitates the synchronous display and navigation of multiple datasets for viewing data and easy follow-up comparison. The summary report of findings helps the user to track findings and note changes, such as shape, size, or overtime.

(2) Vessel Review and Analysis Application
Vessel Review and Analysis application is an option intended for viewing the anatomy and pathology of a patient's coronary arteries.
Physicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, curved MPR vessel view, and straightened MPR view with cross sections of the vessel. Physicians can semi-automatically stenosis measurements, and maximum and minimum lumen diameters. In addition, physicians can also measure vessel dimensions along the centerline in curved MPR view and examine Hounsfield unit or signal intensity statistics.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Summary Prepared Date: 8/28/2015

Submission Sponsor (Manufacturer):

Dexin Medical Imaging Technology Co., Ltd.
227 Chongye Street,
Weinan High-tech Zone, Weinan, Shaanxi, China 714000

Contact Person
Name: Wang, Yu
Title: QA Manager

Submission Correspondent (Agent):

Mr. Anthony Hopkins
Regulatory Affairs Specialist

Mr. Leon Lu
Director of Quality and Regulatory Affairs

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Trade/Device Name:
FACT Medical Imaging System

Device Class: II
Classification Name: Medical Image Processing Software
Regulation Number: 21 CFR. 892.2050

Section5 510(k) Summary

Product Code: LLZ
Review Panel: Radiology
Predicate Device:

- K071331
  Vital Images, Inc.
  Vitrea, version 4.0 Medical Image processing Software

- K120484
  Mevis Medical Solutions
  Visia™ Oncology

- K083227
  VIDA Diagnostics
  VIDA Pulmonary Workstation 2 (PW2)

Device Description:

The FACT Medical Imaging System is self-contained, non-invasive medical image processing software. It can be marketed as software only, as well as packaged with standard off-the-shelf PC hardware. It can operate as a stand-alone workstation or in a distributed server-client configuration across a computer network.

The FACT Medical Imaging System allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. This device addresses physicians' needs through various application options for pulmonary and vessel applications.

Over the counter use: No
Duration and type of contact: N/A
Single use: No
Sterile: No

Section5 510(k) Summary

Indication for Use:

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In addition, the FACT Medical Imaging System has the following indications:

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Pulmonary Review and Analysis application is an option that is intended for supporting physicians in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from pulmonary CT images. Three-Dimensional segmentation and isolation of sub-compartments, volumetric analysis, density evaluations, and reporting tools are combined with a dedicated workflow.

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Vessel Review and Analysis application is an option intended for viewing the anatomy and pathology of a patient’s coronary arteries.

Physicians can select any artery to view the following anatomical references: the highlighted vessel in 3D, curved MPR vessel view, and straightened MPR view with cross sections of the vessel. Physicians can semi-automatically stenosis measurements, and maximum and minimum lumen diameters. In addition, physicians can also measure vessel dimensions along the centerline in curved MPR view and examine Hounsfield unit or signal intensity statistics.

Software Development:

The FACT Medical Imaging System was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and maintenance.

Comparison to Predicate Devices:

Indications For Use Statement						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A
1	Acquiring images from a variety of imaging devices	Same	Same	Same	Similar	Same
2	Processing, review, analysis, communication and media interchange of multi-dimensional digital images	Same	Same	Same	Similar	Same
3	To be used for supporting physicians in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from pulmonary CT images.	Same	None	Similar	Same	Same
4	To be used for viewing the anatomy and pathology of a patient's coronary arteries	Same	Same	None	None	Same
Standards Met						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A
5	Conforms to the essential requirements of the DICOM standard for data exchange (PS 3.3 – PS 3.12)	Same	Same	Same	Same	Same
Design						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A
6	Software device that operates on off-the-shelf hardware	Same	Same	Same	Same	Same
7	Device is a system composed of multiple components that work stand-alone and in concert	Same	Same	Same	Partial, stand-alone only	Same
8	Web-based client	Same	None	None	None	N/A. But this web-based feature has been included by many PACS, such as K131424 (Product name: miPlatform medical imaging suite, Company name: Hinacom

						Software and Technology Ltd. Co.). This new feature won't affect the safety and effectiveness of the subject device.
9	Operating System	Windows	Windows	Windows	Linux	Same
Functions and Capabilities – General Functions						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A
10	DICOM Image Import/ Export (Support DICOM Storage, Query/Retrieve, and Print)	Same	Same	Same	Partial, PW2 support DICOM Image Import	Same
11	Present a study list	Same	Same	Same	Same	Same
12	2D image reading (Support image annotation, measurement and cine)	Same	Same	Same	Same	Same
13	Synchronized stacking	Same	Same	Same	None	Same
14	3D visualization (Support MPR, MIP, volume rendering)	Same	Same	Same	Same	Same
Functions and Capabilities – Pulmonary Review and Analysis Application						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A
15	Segmentation of left / right lungs	Same	None	Same	Same	Same
16	Segmentation of pulmonary fissures/ lobes	Same	None	None	Same	Same
17	Segmentation of pulmonary airways tree	Same	None	Same	Same	Same
18	Segmentation of pulmonary vessels	Same	None	Same	Same	Same
19	Segmentation of suspicious nodules	Same	None	Same	None	Same
20	Export reports (including key image and measurement)	Same	Same	Same	Partial. Export measure-ment only	Same
21	Automated image registration of two datasets for follow-up comparison	Same	None	Same	None	Same
22	Virtual fly-through the airways	Same	None	None	Same	Same
23	3D visualization of pulmonary sub-compartments	Same	None	Same	Same	Same
24	Volumetric analysis (Support size, density, volume)	Same	None	Same	Same	Same
25	airway lumen and wall thickness measurements	Same	None	None	Same	Same
Functions and Capabilities – Vessel Review and Analysis Application						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A

26	Segmentation of coronary vessels	Same	Same	None	None	Same
27	3D visualization of coronary vessels	Same	Same	None	None	Same
28	Vessel centerline review	Same	Same	None	None	Same
29	Curved MPR vessel view	Same	Same	None	None	Same
30	Measurement of vessel dimensions	Same	Same	None	None	Same
31	Measurement of stenosis	Same	Same	None	None	Same
32	Exporting reports	Same	Same	None	None	Same
Other Areas of Comparison						
		Subject Device	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 4**	**Discussion**
		FACT Medical Imaging System	Vitrea, version 4.0	Visia™ Oncology	VIDA Pulmonary Workstation 2 (PW2)	N/A
33	Target population	No restriction	Same	Same	Same	Same
34	Intended user	to be used by trained professional-s only	Same	Same	Same	Same
35	Energy used and/or delivered	Electric power supply to computer hardware only	Same	Same	Same	Same
36	Materials	N/A	N/A	N/A	N/A	N/A
37	Biocompatibility	N/A	N/A	N/A	N/A	N/A
38	Compatibility with environment and other devices	Interoperation with other devices based on consensus standards on data exchange (DICOM)	Same	Same	No direct interface with any CT or data collection equipment	Same

The proposed FACT Medical Imaging System has similar intended use as the predicate devices, Vitrea Medical Image processing software (k071331), Visia™ Oncology (K120484), and VIDA Pulmonary Workstation 2 (PW2) (k083227).

The FACT Medical Imaging System is similar in overall design, principal of operation and configuration compared to the predicate devices. These devices are medical application software and they all provide 2D & 3D image visualization and manipulation tools for medical image analysis.

The FACT Medical Imaging System and its predicate device, Vitrea Medical Image processing software, both allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices, support the DICOM protocol for communication of images with other medical imaging devices, and support the workflows, UI, and functions for vessel analysis scope.

The FACT Medical Imaging System and its predicate devices, Visia™ Oncology and VIDA Pulmonary Workstation 2 (PW2) support the workflows, UI, and functions for pulmonary analysis scope.

No new issues of safety or effectiveness are introduced by using this proposed device. In summary, this proposed device is substantially equivalent to the predicate devices in the areas of technical characteristics, general function, application, and intended use. This device does not raise any new potential safety risks and is equivalent in performance to the predication devices.

Discussion of Non-Clinical Tests Performed:

The following non-clinical tests have been performed:

- Functional test
- Functional regression test
- Performance test
- Portability test
- Graphical user interface test
- Usability test
- Interoperability test
- Measurement accuracy evaluation and validation:
  - Accuracy of pulmonary segmentation and measurements
  - Accuracy of fissure segmentation and measurements
  - Accuracy of airway segmentation and measurements
  - Accuracy of vessel segmentation and measurements

The FACT Medical Imaging System was tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of this device, which is found to be safe and effective and substantially equivalent to the currently-cleared predication devices. Pass/Fail criteria were based on the requirements and intended use of the proposed device. Test results showed that all tests successfully passed.

Discussion of Clinical Tests Performed:

None

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. It is the user's responsibility to ensure that display quality, environmental lighting and other

possible distractions are consistent with the clinical environment. The hardware components specified are all 'off the shelf' computer components.

Conclusion:

The proposed device is as safe and effective as the predicate devices. The proposed device has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the proposed device and its predicate devices raise no new issues of safety or effectiveness. Thus, the proposed device is considered to be substantially equivalent to its predicate devices.